MAY 1 8 2005

K050753

4100 E. Milham Avenue
Kalamazoo, MI 49001
t: 269 323 7700 f: 800 965 6505
www.stryker.com

stryker

Instruments

Summary of Safety and Effectiveness

Device Sponsor: Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, MI 49001
269-323-7700
Registration No.: 1811755

Device Name: Trade Name: Stryker Discmonitor
Common Name: Discography Pressure Monitor
Classification Name: Injector and Syringe, Angiographic
21 CFR§ 870.1650, DXT

Predicate Devices: Merit Medical 30ATM Monarch – K011811
Merit Medical Universal Fluid Dispensing Syringe – K973230
Merit Medical Intellisystem II Color Monitor – K993341
Physician Industries Accumeter – K033739
Atrion Medical QL™ Fluid Dispensing Syringe – K020333

Description: The Stryker Discmonitor is a sterile, disposable device used to inject fluid into the intervertebral disc nucleus during discography procedures. The device will measure the pressure of the fluid and display it in a digital format. The physician can control the pressure of the fluid and the rate of injection using the device. As additional information, the device will also measure the volume of fluid injected into the disc and the amount of time each disc is pressurized. The device will save the pressure and volume over time during the procedure. The physician will be able to manually save key data points for each disc. These points may be recalled later and are highlighted on the printout in both a graphic and tabular format.

Intended Use: The Stryker Discmonitor is used to inject fluids into the intervertebral disc nucleus during discography procedures and monitor the pressure of that fluid.

Substantial Equivalence (SE) Rational: The Stryker Discmonitor is equivalent in intended use, safety, and effectiveness to existing devices being marketed by Merit Medical.

Safety and Effectiveness: The Stryker Discmonitor does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker Discmonitor is substantially equivalent to these existing devices.

Signed: _____ Dated: May 6, 2005
Jean W. Sheppard
Regulatory Affairs Analyst

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Mr. Jean W. Sheppard
Regulatory Analyst
Stryker Instruments
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K050753
Trade/Device Name: Styker Discmonitor
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: May 6, 2005
Received: May 10, 2005

Dear Mr. Sheppard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

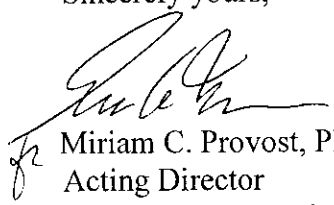
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050753

Indications for Use Statement

510(k) Number: **K050753**

Device Name: Stryker Discmonitor

Indications For Use: The Stryker Discmonitor is used to inject fluids into the intervertebral disc nucleus during discography procedures and monitor the pressure of that fluid.

Prescription Use ____X_______ AND/OR Over-The-Counter Use ________
(Per 21 CFR 801Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

... Restorative
... Devices

K050753